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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,258	08/25/2006	Colin Louis Masters	16453	6259

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EXAMINER	
CRUZ, KATHRIEN ANN	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
04/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,258	MASTERS ET AL.	
	Examiner	Art Unit	
	KATHRIEN CRUZ	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 40-52 are pending.

Applicants response filed on January 6, 2009 has been received and entered in the application.

Priority

This application is a 371 of PCT/AU04/00427 (dated 04/02/2004)

which claims benefits of provisional application 60/460/460,155 (dated 04/03/2003).

Action Summary

Claims 40-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerolymatos (U.S. Patent 5,994,323) and in view of Boudrie et al (U.S.Publication 2002/0111384) and in further view of Kaminski (U.S. Patent 5,889, 033) is maintained.

Response to Arguments

Applicants argue that HD and AD are distinct disorders that differ in their genetic orgins, fundamental pathologies and patient symptoms, and therefore therapeutic treatments for one disease would not be expected to necessarily apply to the other.

This argument has been fully consider but has not been found persuasive. Because the **symptoms** of Alzheimer's disease such as forgetfulness, loss of concentration, confusion, poor judgment, language disturbance, agitation, withdrawal and hallucination as taught by Boudrin et al. overlap with the **symptoms** of Huntington's disease such as cognitive symptom (i.e. slowness in thinking, memory loss), emotional symptoms (i.e. hallucination), impairment in voluntary movements, involuntary movements as taught by Kaminski. Since these symptoms do overlap and the symptoms of HD and AD are known in the art to be treated with the same medical regimen, It would have been obvious to one of ordinary skills to obtain expected success in the treatment of HD patient with clioquinol with the claimed dosages of Gerolymatos in view of Boudrie and in further view of Kaminski.

For the ease of the applicant the previous office action dated October 6, 2008 is reproduced below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 40-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerolymatos (U.S. Patent 5,994,323) and in view of Boudrie et al (U.S.Publication 2002/0111384) and in further view of Kaminski (U.S. Patent 5,889, 033).

Gerolymatos teaches that clioquinol is used in the delay of the onset or evolution or aggravation of the **symptoms and signs of Alzheimer's disease** (column 7, lines 3-5). Gerolymatos teaches a method of treating Alzheimer's and Parkinson's disease with a suitable (therapeutically effective) amount of clioquinol in the pharmaceutical composition is from about 5 to 250 mg (column 8, lines 48-50 and claims 20, 25-27). Gerolymatos teaches a suitable amount of vitamin B_{12}, effective to inhibit clioquinol related side effects, in the pharmaceutical composition is about 5 μg to 2 mg. Clioquinol and vitamin B_{12} can be in the same composition for administering in combination concurrently, or in different composition for administering concurrently but separately or sequentially (column 8, lines 58).

Gerolymatos does not specifically teach the treatment of **symptoms of Huntington's disease** with clioquinol or disclose specific dose range of 100 to 1,500 mg/day of clioquinol.

Boudrine et al teaches that **symptoms of Alzheimer's disease** include, **forgetfulness, loss of concentration, confusion, poor judgment, language disturbance, agitation, withdrawal and hallucination** (paragraphs 0007 and 0008) and it impairs a person's ability to govern emotions, recognize errors and patterns, **coordinate movements** and **remember stored cognitive function** (paragraph 0003). Boudrine et al teaches that Alzheimer's disease is a common and complex disorder characterized by adult-onset progressive dementia (paragraph 0003).

Kaminski teaches that **symptoms of Huntington's disease** include, involuntary movements, impairment in voluntary movements, emotional symptoms (i.e. hallucinations) and cognitive symptoms (i.e. apathy, slowness in thinking, decrease in attention, decreased in ability to shift set, memory loss) (column 5, lines 37- 47).

It would have been obvious to one of ordinary skills in the art to employ clioquinol for the treatment of **symptoms of Huntington's disease** such as involuntary movements, impairment in voluntary movements, emotional symptoms (i.e. hallucinations) and cognitive symptoms (i.e. apathy, slowness in thinking, decrease in attention, decreased in ability to shift set, memory loss) because Gerolymatos teaches that clioquinol is effective for the treatment of the symptoms of Alzheimer's disease which are characterized by having similar symptoms as Huntington's disease. There is a great over lap in symptoms of Huntington's disease and symptoms of Alzheimer's disease.

One would be motivated to make such modifications in order to achieve an expected benefits of clioquinol in the known treatment of symptoms involving Alzheimer's that over lap with the symptoms of Huntington's disease.

There is a reasonable expectation of successfully treating **symptoms** of Huntington's disease such as involuntary movements, impairment in voluntary movements, emotional symptoms (i.e. hallucinations) and cognitive symptoms (i.e. apathy, slowness in thinking, decrease in attention, decreased in ability to shift set, memory loss) because clioquinol is effective in treating such **symptoms** as taught by Gerolymatos in view of Boudrine et al.

It would have been obvious to one skilled in the art at the time of the invention was made to optimize the dosage of clioquinol. Gerolymatos teaches a dosage range of 5 to 250 mg daily for the treatment of **symptoms** of Alzheimer's disease. Further, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude; for instance, an extremely heavy patient or one having an unusually severe symptoms associated with Huntington's disease would require a correspondingly higher dosage. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity. The specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition of the patient, the duration of treatment , the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier

employed, the solubility of the formula therein and the dosage regimen desired for the composition.

For these reasons, the claimed subject matter is deemed to fail to be patentably distinguishable over the state of the art as represented by the cited reference. The claims are therefore, properly rejected under 35 U.S.C. 103.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Claims 40-52 are rejected.

No claims allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached on Mon - Thurs 7:00am - 5:00pm with every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KATHRIEN CRUZ/
Examiner, Art Unit 1617

/San-ming Hui/
Primary Examiner, Art Unit 1617